



FEB 10 1998

0556 '98 MAR 24 P2:42

Ms. Patricia Babik
Regulatory Correspondent
LPG USA
3101 North Federal Highway
Suite 301
Ft. Lauderdale, Florida 33306

Dear Ms. Babik:

This is in response to your letter of January 8, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that LPG USA, is making the following statements, among others, in product promotional material for the product "Endermologie Weight Management Formula:"

- "...accelerates healing"
- "Lowers cholesterol and triglyceride levels"
- "May act as a mild laxative"
- "May lower cholesterol"
- "Diuretic, i.e. promotes management of excess body fluid"
- "...diminishing cravings for both sugar and alcohol"
- "Relieves excess water retention and constipation"

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate hypercholesterolemia, constipation, alcohol dependence, abnormal fluid retention and general illnesses (i.e., "accelerates healing"). These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 USC 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also contained labels for the products "Endermologie Weight Management Formula" and "Endermologie Cleansing Formula." The labels for the Weight Management Formula and the Cleansing Formula bear the claims "Fat burner, antioxidant, metabolic facilitator, diuretic" and "Reduces water retention, boosts metabolism, cleans system," respectively. Under 21 USC 343(r)(6), the labeling of a dietary supplement may bear certain

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claims, including claims that describe the role of a dietary ingredient intended to affect the structure or function in humans. However, in order for dietary supplement labeling to bear a claim under this section, a manufacturer must comply with all requirements set forth in 21 USC 343(r)(6), including the requirement that the claim contain the disclaimer described in that section¹.

The labels for these two products do not bear the mandatory disclaimer and therefore, your products may be subject to regulation as drugs under 21 USC 321(g)(1)(C) as articles (other than food) intended to affect the structure or any function of the body of man. Moreover, as discussed above, one claim on the label of the Weight Management Formula (i.e., "diuretic") suggests that this product is intended for use as a drug within the meaning of 21 USC 321(g)(1)(B), and therefore that it is subject to regulation under the drug provisions of the act.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Florida District Office, Compliance Branch, HFR-SE240

¹FDA has issued regulations governing the display of the disclaimer on labels of dietary supplements in 21 CFR 101.93(b) (copy of the September 23, 1997 final rule is enclosed). The regulations will become effective March 23, 1999.

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file, OSN#56561)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:1/21/98

init:GCF-1:LNickerson:2/6/98

f/t:rjm:HFS-456:2/9/98:56561.adv:disc25



Thursday, January 08, 1998

Office of Special Nutritionals
HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St. SW
Washington, DC 20204

RE: Notification of Dietary Supplements

To Whom It May Concern:

In accordance with the Food Labeling Act 21 CFR § 101.93, this is to inform you that LPG USA will distribute dietary supplements which bear the titles and claims "Weight Management Formula" and "Cleansing Formula".

In addition to the attached labeling for the products, below you will find the pertinent details regarding manufacturer and distributor of the products.

Identification of Manufacturer and Distributor

Manufacturer: **Sun Ten Laboratories**
(and packer) 9250 Geronimo Road
Irvine, CA 92618

Distributor: **LPG USA**
3101 N. Federal Highway
Suite 301
Ft. Lauderdale, FL 33306

Names of Dietary Supplements and Text of Statements Made

1. Weight Management Formula

This formula is designed to supplement the diet and enhance a weight loss program. In addition to biochemical mechanisms, this formula has a bioenergetic action and nourishing herbs enhance energy flow and production.

Thermogenesis refers to the body's conversion of ingested calories into heat instead of fat. Stored fat can also be reduced by the same process. LPG's Weight Management Formula includes thermogenic ingredients such as: Kola Nut, Gotu Kola, Green Tea, and Guarana, Chromium and Gymnema.

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Kola Nut, Green Tea, and Guarana are natural sources of caffeine which helps affect the appetite while giving a boost of energy.

Antioxidants are provided to prevent cell damage from free radicals. These are the unstable molecules that are a) created in the body during the normal biochemical processes, b) produced by ingested toxins. Free radicals cause fluid retention, accelerated aging, and impaired immunity to illness.

Antioxidants neutralize free radicals, and help to detoxify and protect the body. The antioxidants in the Weight Management Formula include Vitamins C and E, Zinc, Copper, Manganese, Milk Thistle, Grape Seed Extract, and Astragalus.

2. *Cleansing Formula*

Based on traditional Chinese herbal formulas used for over 800 years, the Cleansing Formula provides many functional features. LPG's Cleansing Formula:

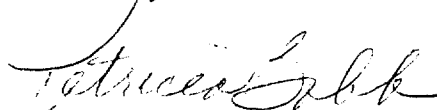
- Clears toxins from the body through skin, excretory and digestive systems
- Reduces water retention
- Tones the skin and underlying tissues
- May promote bowel movements
- Promotes water metabolism
- Promotes lipid metabolism
- Inhibits cholesterol absorption

The Cleansing Formula for Endermologie® promotes the elimination of both the toxic by-products of metabolism, as well as the environmental toxins that are otherwise stored indefinitely in the fat cells. Ingredients include: Crataegus extracts (fruit), Alisma (rhizome), Rhubarb (rhizome), Licorice (root), Siler (root), Ginger (rhizome), Platycodon (root), Gardenia (fruit), Forsythia (fruit), Schizonepata (whole plant), Mentha (whole plant), Atactylodes (rhizome), Scute (root), Tang-kuie (root), Peony (root) and Cridium (rhizome).

Research for the substantiation of the claims is found in the following sources: Krause's Food, Nutrition and Diet Therapy, Earl Mendell's Herb Bible, and various sources from Medline. Copies of our substantiation are available upon request.

Should you require additional information, please feel free to contact me at 800.222.9311.

Cordially,



Patricia Babik
Regulatory Correspondent
g: a/c/r/Supp_not
enc.



DIRECTIONS: As a dietary supplement, take two (2) capsules with 8 ounces of water, 30 to 40 minutes before each meal.

NOTE: If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.

**DO NOT USE IF SAFETY SEAL
IS BROKEN OR MISSING.**

GUARANTEE: This product contains no added sugar, salt, yeast, wheat or dairy products. No preservatives, artificial colors or flavors.

**STORE IN A COOL DRY PLACE.
KEEP OUT OF REACH OF CHILDREN.**

Exclusively Formulated by:
BioBalance International, Inc.
377 South Nevada St.
Carson City, NV 89703

Distributed by: LPG USA
3101 N. Federal Highway - Suite 301
Fort Lauderdale, FL 33306

ENDERMOLOGIE

ENDERMOLOGIE[®]

Weight Management Formula



**Fat Burner
Antioxidant
Metabolic Facilitator
Diuretic**

180 Capsules 500 mg each

As a dietary supplement, six (6) capsules daily provide:

		% USA RDA*
Kola Nut Extract.....	30 mg	**
Green Tea Extract.....	60 mg	**
Guarana Extract.....	3 mg	**
Vitamin C (Ascorbic Acid).....	60 mg	200
Vitamin E (Acetate).....	15 iu	50
Zinc (Amino Acid Chelate).....	10 mg	133
Copper (Amino Acid Chelate).....	1 mg	50
Manganese (Amino Acid Chelate).....	2 mg	**
Milk Thistle Extract.....	25 mg	**
Grape Seed Extract.....	10 mg	**
Astragalus.....	50 mg	**
Pyruvate.....	100 mg	**
Chromium (Nicotinate Glycinate).....	200 mcg	**
Iodine (Atlantic Kelp).....	150 mcg	**
Gotu Kola Extract.....	5 mg	**
Bladderwrack.....	50 mg	**
Butcher's Broom.....	50 mg	**
Citrimax®(Potassium).....	1,500 mg	**
Gymnema Sylvestre Extract.....	30 mg	**
Guar Gum.....	18 mg	**
L-Tyrosine.....	250 mg	**
L-Glutamine.....	250 mg	**
Chinese herbal formulation containing extracts of Dandelion (Taraxacum Herba, whole plant), Pteris (Pteris Herba, whole plant), Ho Shou Wu (Polygonum Multiflorum Root, root), Cassia (Cassia Torae Semen, seed), Chih shih (Aurantii Fructus Immaturus, fruit), Alisma (Alismatis Rhizoma, rhizome) and Schizandra (Schizandrae Fructus, fruit).....		
	100 mg	**

*Percent of the United States Recommended Daily Allowances
**No U.S. RDA has been established

DIRECTIONS: As a dietary supplement, take one (1) capsule, three times daily, before each meal, or as prescribed by your Health Care Practitioner.

NOTICE: This product contains Rhei Rhizoma, Rhubarb root, which may promote elimination. Do not use if you have or develop diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.

GUARANTEE: This product contains no added sugar, salt, yeast, wheat or dairy products. No preservatives, artificial colors or flavors.

**STORE IN A COOL DRY PLACE.
KEEP OUT OF REACH OF CHILDREN.**

Distributed by: LPG USA
3101 N. Federal Highway - Suite 301
Fort Lauderdale, FL 33306

ENDERMOLOGIE[®]

Cleansing Formula



Reduces Water Retention
Boosts Metabolism
Cleans System

90 Capsules 650 mg each

As a dietary supplement, three (3) capsules daily provide 1950 mg of a proprietary Chinese herbal formulation containing extracts of Crataegus (Crataegi Fructus, fruit), Alisma (Alismatis Rhizoma, rhizome), Rhubarb (Rhei Rhizoma, rhizome), Licorice (Glycyrrhizae Radix, root), Siler (Ledebouriellae Radix, root), Ginger (Zingiberis Rhizoma, rhizome), Platycodon (Platycodi Radix, root), Gardenia (Gardenia Fructus, fruit), Forsythia (Forsythiae Fructus, fruit), Schizonepeta (Schizonepetae Herba, whole plant), Mentha (Menthae Herba, whole plant), Atractylodes (Atractylodis Rhizoma, rhizome), Scute (Scutellariae Radix, root), Tang-Kuei (Angelicae Radix, root), Peony (Peony Radix, root) and Cridium (Ligustici Rhizoma, rhizome).

Exclusively formulated by:
BioBalance International, Inc.
377 South Nevada St.
Carson City, NV 89703

ENDERMOLOGIE



DIETARY SUPPLEMENTS
ENHANCING THE RESULTS OF THE ENDERMOLOGIE® LIFESTYLE

WHY DIETARY SUPPLEMENTS?

As health care practitioners, you may often observe your patients trying to incorporate the Endermologie® lifestyle. For many, this will mean a change in dietary patterns or exercise habits, or both. For those whose body contouring goals include weight management, LPG USA is please to introduce you to two all natural proprietary formulas to help you achieve success.

With proper diet and exercise, the combined mechanical massage and metabolic approach offered by Endermologie® provides an optimal treatment program.

THE MANUFACTURING PROCESS

LPG's dietary supplements are produced in a state-of-the-art manufacturing facility in the United States. The plant has developed major technological advances and contains sophisticated processing equipment. New and improved methods of preparation provide a safe, effective and predictable way for all natural, herbal formulas to restore and maintain balance and harmony.

GUIDELINES TO TAKE THE DIETARY SUPPLEMENTS

Before using the Weight Management and Cleansing Formula, it is important to read this information regarding herbal supplementation.

Herbs perform many useful functions in the body but they must be used appropriately. Although herbal remedies are less likely drives to cause side effects, herbs nevertheless can be very potent if taken beyond the recommended doses. You should also be aware that some herbs that may interact negatively with prescribed medications.

Keep in mind the following guidelines when taking the supplements.

- 1) Always take supplements with a full glass of water. Nutritional supplements are concentrated and can overburden the liver if not enough liquid is consumed with these cellular nutrients.
- 2) Before you begin taking either formula on a regular basis, test the supplements one at a time to find out if you have a reaction to them. Increase your intake of these products gradually to give your body time to adjust to each formula, and should side effects become unbearable, discontinue use.

WEIGHT MANAGEMENT FORMULA

This formula is designed to supplement the diet and enhance a weight loss program. In addition to biochemical mechanisms, this formula has a bioenergetic action and nourishing herbs enhance energy flow and production.

Thermogenesis refers to the body's conversion of ingested calories into heat instead of fat. Stored fat can also be reduced by the same process. LPG's Weight Management Formula includes thermogenic ingredients such as: Kola Nut, Gotu Kola, Green Tea, and Guarana, Chromium and Gymnema.

Kola Nut, Green Tea, and Guarana are natural sources of caffeine which helps affect the appetite while giving a boost of energy.

Antioxidants are provided to prevent cell damage from free radicals. These are the unstable molecules that are a) created in the body during the normal biochemical processes, b) produced by ingested toxins. Free radicals cause fluid retention, accelerated aging, and impaired immunity to illness.

Antioxidants neutralize free radicals, and help to detoxify and protect the body. The antioxidants in the Weight Management Formula include Vitamins C and E, Zinc, Copper, Manganese, Milk Thistle, Grape Seed Extract, and Astragalus.

Directions: As a dietary supplement, take two (2) capsules with eight (8) ounces of water, 30-40 minutes before each meal.

A special note to individuals who may be sensitive to experiencing increased energy levels at night. If you prefer to take a fewer capsules in the evening you may consider taking the supplements in the morning and then late in the afternoon.

These supplements were designed specifically for patients participating in an ongoing Endermologie program. It is recommended that they be used consistently. Should you wish, they may be incorporated into your permanent nutrition program.

The following page provides a detailed list of the ingredients with their functions.

VITAMINS

- | | |
|------------------|---|
| <u>Vitamin C</u> | • Antioxidant, immune stimulant, accelerates healing, tissue repair |
| <u>Vitamin E</u> | • Antioxidant, immune support, enhances circulation and wound healing |

MINERALS

- | | |
|--|---|
| <u>Chromium</u>
<u>Polynicotinate</u> | <ul style="list-style-type: none"> • Works with insulin to balance blood sugar levels • Promotes fat management • Lowers cholesterol and triglyceride levels |
| <u>Zinc Chelate</u>
(pronounced
"key -late") | <ul style="list-style-type: none"> • Greater tissue deposition of zinc (Weber State) • Essential for tissue/wound healing, as well as hormone production |
| <u>Copper Chelate</u> | <ul style="list-style-type: none"> • Antioxidant • Required for connective tissue health, maturation of collagen, and elastin formation • Oxidation of fatty acids |
| <u>Manganese</u> | <ul style="list-style-type: none"> • Often deficient, it is an essential mineral for repair of connective tissue and bones |
| <u>Chromium</u> | <ul style="list-style-type: none"> • Works with insulin to balance blood sugar levels • Promotes fat management • Lowers cholesterol and triglyceride levels |

HERBS

- | | |
|--|---|
| <u>Rhubarb</u> | <ul style="list-style-type: none"> • Affects appetite • May act as a mild laxative |
| <u>Cassia seed</u> | <ul style="list-style-type: none"> • Inhibits the absorption of cholesterol in the intestines |
| <u>Ho Shou Wu,</u>
<u>Alisma</u> | <ul style="list-style-type: none"> • May lowers cholesterol and triglycerides |
| <u>Citrimax®</u>
(Garcinia
Cambogia) | <ul style="list-style-type: none"> • Affects the appetite • Increases energy • Inhibits fat synthesis |
| <u>Green Tea</u>
(contains
caffeine) | <ul style="list-style-type: none"> • May lower cholesterol • Promotes fat burning • Stimulates the central nervous system and affects the appetite • Provides strong antioxidants |

These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

Guarana
(contains
caffeine)

- Stimulant
- Diuretic, i.e. promotes management of excess body fluid

Kola Nut
(centella
asiatica)

- Burns stored fat without burning muscle tissue, thus increasing lean body mass.

Gotu Kola

- Helps to release stored water
- Decreases capillary permeability
- Enhances blood flow by strengthening the veins and capillaries

Milk Thistle

- Supports the liver, the main organ for cleansing
- Potent antioxidant

Gymnema
Sylvestre

- Suppresses the taste of sweet food, thus reducing sugar cravings
- Prevents sugar absorption by the intestine during digestion, thereby lowering blood sugar

OTHER NUTRIENTS

L-Glutamine

- Affects appetite and reduces food-binging by acting as a substitute for glucose, supplying brain fuel when blood sugar is low, thus diminishing cravings for both sugar and alcohol.
- Helps to maximize muscle growth
- Increases growth-hormone levels which increases lean body mass
- Maintains a healthy digestive tract

Grape Seed

- Powerful antioxidant

Guar Gum

- Curbs the appetite
- May reduce cholesterol and triglycerides
- Binds with toxic substances for rapid waste elimination

Pyruvate

- Antioxidant properties
- Increases lean muscle mass
- Increases fat and weight management and inhibits fat "regain" – minimizing the "yo -yo" effect
- Helps to burn fat

Butcher's
Broom

- Relieves excess water retention and constipation
- Improves circulation in hands and feet
- May have anti-inflammatory properties
- Reduces capillary fragility

These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

Astragalus

- Enhances circulation
- Increases metabolism
- Enhances energy

CLEANSING FORMULA

Based on traditional Chinese herbal formulas used for over 800 years, the Cleansing Formula provides many functional features. LPG's Cleansing Formula:

- Clears toxins from the body through the skin, excretory and digestive systems
- Reduces water retention
- Tones the skin and underlying tissues
- May promote bowel movements
- Promotes water metabolism
- Promotes lipid metabolism
- Inhibits cholesterol absorption

The Cleansing Formula for Endermologie® promotes the elimination of both the toxic by-products of metabolism, as well as the environmental toxins that are otherwise stored indefinitely in the fat cells.

Directions: As a dietary supplement, take one (1) capsule, three (3) times daily before each meal.

This formula was designed to create a cleansing effect on the body that eliminates toxins which have accumulated over time. Individuals who have not followed a cleansing program before may experience some side effects including increased bowel movements, nausea, and fatigue.

It is very important that one begins the cleansing formula gradually, with adequate water intake. This will reduce the chance of side effects as well as allow the body time to adjust to a new cleansing process. Some individuals may prefer to use the Cleansing Formula only at bedtime due to the loosening of the bowels.

Once an initial cleansing program is reached, you may prefer to incorporate the supplement into a program that is used for one week per month.